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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/763,370	02/21/2001	Etsuro Ogata	OGATA4	9907

1444 7590 10/22/2002

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EXAMINER

HARRIS, ALANA M

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 10/22/2002

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/763,370

Applicant(s)

OGATA ET AL.

Examiner

Alana M. Harris, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION:

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 July 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 8-12, 14 and 15 is/are allowed.
- 6) ☒ Claim(s) 2-7, 13 and 16-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 10 & 12.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Request for Continued Examination

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 29, 2002 has been entered.

2. Claims 2-18 are pending.

Claims 2-6 have been amended.

Claim 1 has been cancelled.

Claim 18 has been added.

Claims 2-18 are examined on the merits.

Withdrawn Rejections

Claim Rejections - 35 USC § 102

3. The rejection of claims 2-5 under 35 U.S.C. 102(b) as being anticipated by Plebani et al. (Clinical Biochemistry 29(1): 67-72, February 1996) is withdrawn. Claim 1 has been cancelled.

New Grounds of Objection and Rejection

Claim Objections

4. Claim 6 is objected to because of the following informality: it contains the misspelled word "metasasis". Correction is required.
5. Claim 18 is objected to because of the following informality: it improperly depends from claim 3. Claim 18 references a marker that reflects the action of osteoclasts, whereas claim 3 references a marker that reflects the activity of osteoblasts.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
7. Claims 2-7, 13, 16, 17 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
 - a. Claim 6 is vague and indefinite in the recitation "diagnosed correctly". It is routine in the art to diagnose a disease or condition to the best of one skilled in the art's ability. The term "correctly" seems to be superfluous.
 - b. Claims 6 and 16 are vague and indefinite in the recitation "crossover index or the ratio". According to a response filed December 3, 2001 as Amendment B, page 9 it is asserted that the crossover index is the value obtained by dividing one of two measure values by the other. This definition also seems applicable to the term "ratio".

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The terms appear to be redundant. Furthermore, it is not clear where in the specification these two terms are defined.

c. The terms “crossover index” and “ratio” in claims 6, 7, 16 and 17 are vague and indefinite. It is not clear from the claims how the resulting product, number or value from the crossover index or ratio is of diagnostic significance. Furthermore, it is not clear how these values are to correlate with metastasis.

d. Claims 6, 7, 16 and 17 are vague and indefinite. The crossover index allegedly utilizes two measured values. The product of the crossover index yields a number relevant to diagnosing bone metastasis. The claims read on assessing several different values and it is not clear which one is A and which one is B, which would render A/B, hence the crossover index. As the claims currently read there are multiple values to be obtained. In the instant case of claim 6 the crossover index is based between (1) a marker associated with the phase of osteoblast proliferation and matrix formation and (2) a marker that reflects the action of osteoclasts. The claim continues to state that a crossover index calculation comprises (1) a marker associated with the phase of calcification, (2) a marker associated with the phase of matrix calcification, (3) a marker associated with the phase of matrix maturation, and (4) a marker associated with bone type I collagen.

Additionally, in the instant case of claim 7 the crossover index is based on (1) osteocalcin and PICP or osteocalcin and PINP and (2) osteocalcin and BALP. Furthermore, there is the measured value of ICTP, which seems to be applied to both

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crossover indices. ICTP seems to be component C. Neither claim clearly or implicitly states which two factors are to be used in calculating the crossover index.

e. Claim 13 is vague and indefinite. Claim 13 states the markers that are associated with the activity of osteoblasts: PICP, PINP, BALP and osteocalcin. It is not clear why osteocalcin is presented, as well as presented twice. Osteocalcin is an osteoclastic marker and not an osteoblast marker.

Allowable Subject Matter

8. Claims 8-12, 14 and 15 are allowed.

9. Claims 2-18 are free of the art.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (703) 306-5880. The examiner can normally be reached on 6:30 am to 4:00 pm, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D. can be reached on (703) 308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4315 for regular communications and (703) 308-4315 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0196.

ALANA HARRIS
PATENT EXAMINER



Alana M. Harris, Ph.D.
October 18, 2002